REMARKS

Claims 1-36 are presently pending in the case. Claims 1, 15, 17, 24-29, 32-34, and 36 have been amended. Claims 10, 23, and 33 are withdrawn from consideration but should be considered in that they depend from an allowable base claim, as discussed below.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under 35 USC 102

The Examiner rejected claims 1-9, 12-22, and 24-32 under 35 USC 102(b) as being anticipated by PCT application WO94/16759 to Ritson et al (hereinafter Ritson et al). The rejection is traversed.

Ritson et al does not anticipate claims 1-9 and 12-16. To sustain a section 102 rejection, the reference relied upon, must disclose each and every element of the claimed invention. Non-disclosure of a single element of the claim negates anticipation. Claim 1, for example, is to an aerosol drug delivery system comprising, inter alia, a disposable container adapted to contain a drug formulation and an aerosol generator for aerosolizing the drug formulation in response to manual actuation. In contrast, Ritson et al describes an automatic breath-actuated system (see page 1 lines 4-7). Since Ritson et al does not disclose all positively recited features, a section 102 rejection is precluded. Thus, the Examiner is respectfully requested to reconsider the language of claim 1 and withdraw the rejection thereunder. Claims 2-9 and 12-16 depend from claim 1 and are not anticipated by Ritson et al for at least the same reasons as claim 1.

Independent claims 17 and 28 are also not anticipated by Ritson et al. Claim 17 recites, inter alia, "a container having an amount of a drug formulation that is aerosolized in response to manual actuation." Claim 28 includes, inter alia, a canister that is movable within a housing when manually depressed. As discussed above, Ritson et al does not disclose manual actuation of a system of the type claimed. Accordingly, Ritson et al does not anticipate claims 17 and 28 and claims 18-27 and 29-33 which depend from claim 17 or claim 28.

8

It is respectfully requested that the rejections of claims 1-9, 12-22, and 24-32 under 35 USC 102(b) based on Ritson et al be withdrawn.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 34-36 under 35 USC 103(a) as being unpatentable over Ritson et al in view of U.S. Patent 6,125,844 to Samiotes (hereinafter Samiotes). The rejection is traversed.

Ritson et al and Samiotes do not render independent claim 34 unpatentable. Claim 34 is to a method for administering a nicotine formulation comprising, inter alia, preventing the aerosolization of the nicotine formulation, and aerosolizing the nicotine formulation by manual actuation. As discussed above, Ritson et al does not disclose the manual actuation of a formulation. Samiotes does not make up for this deficiency. Since neither reference teaches the combination of features recited, the references do not render claim 34 unpatentable. Claim 35 depends from claim 34 and is also not rendered unpatentable by Ritson et al and Samiotes. Claim 36 depends from claim 1 which is also not rendered unpatentable by Ritson et al and Samiotes.

Information Disclosure Statement

An information disclosure statement was filed on October 9, 2001 and was received at the PTO on October 15, 2001 (Paper No. 7 according to the Patent Application Information Retrieval service). Applicant requests a copy of the initialed Form 1449 indicating that the Examiner has considered the references.

Conclusion

The Examiner is respectfully requested to consider and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

NEKTAR THERAPEUTICS
(formerly INHALE THERAPEUTIC
SYSTEMS)

By: _____

Dated: __6-5-03__

Guy W. Tucker
Reg. No. 45,302

Please send all correspondence to:
Guy Tucker
Nektar Therapeutics
(formerly Inhale Therapeutic Systems, Inc.)
150 Industrial Road
San Carlos, CA 94070
Phone: (650) 620-5501
Fax: (650) 631-3125

10